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USSN 09/402,737ADDITIONAL FEE

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AUG 13 2002

GROUP 1600REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the following comments.

At the outset, Applicants wish to thank Examiner George for the courtesy of the interview recently accorded Applicants' representative.

During the interview, the Examiner agreed to remove the finality of the present Office Action. The present Office Action now contains a rejection of claims 1-12 based on the combined teachings of Griffin, U.S. Patent No. 5,702,723, and newly cited Nelson, U.S. Patent No. 4,446,140, whereas claims 1-4 had not been amended in the last amendment. Consequently, Applicants' amendment, which did not touch claims 1-4, could not have necessitated this new ground of rejection leveled against claims 1-4. Therefore, the present Office Action should not have been made final. The Examiner agreed, and indicated that the finality of the present Office Action would be withdrawn. An early notice that the finality of the present Office Action has, in fact, been withdrawn is earnestly solicited.

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Claims 1-4 were rejected under 35 USC § 103(a) as being obvious over Griffin alone. In response, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

In response, Applicants point out that the Examiner makes the following statement at the top of page 2 of the Office Action:

“As pointed out by applicant column 4, lines 37-40, [of Nelson] describes a two-stage coated capsule that may have a treatment for a sore throat and a pain reliever or antihistamine. It is the position of the examiner that *both* agents are analgesics. [Emphasis added.]”

Since *three* agents are mentioned, namely 1) the sore throat treatment, 2) the pain reliever and 3) the antihistamine, Applicants were unclear which agents the Examiner referred to when he mentioned “both.” However, Applicants believe this point was clarified during the interview, and the Examiner meant the sole throat treatment and the pain reliever were analgesics.

In response, Applicants point out that there are two possible types of teachings: either 1) an express teaching or 2) an inherent teaching. There is no express teaching in Griffin that the sore throat treatment is an analgesic. Further, since sore throat treatments are not limited to

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analgesics (for example, antibiotics are commonly given to treat some sore throats), that the sore throat treatment is an analgesic is not inherent in Griffin. Consequently, Griffin does not, in fact, render obvious the instantly claimed fixed combination of at least one locally acting analgesic and at least one systemically acting analgesic.

Further on this point, if the Examiner is, in fact, relying on a theory of inherency, then Applicants point out that as indicated by the Board of Patent Appeals and Interferences in *Ex parte Levy*, 17 USPQ2d 1461, 1463-1464 (BPAI 1990):

"[T]he initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests upon the Examiner. * * * In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art. [Emphasis in original.]"

Applicants submit that the Examiner has not discharged this initial burden. As discussed above, known sore throat treatments are not limited to analgesics, but include other treatments, for example, antibiotics, which kill bacteria, and do not necessarily treat pain. Since it is not necessarily the case that sore throat treatments are analgesics, the Examiner's position that the sore throat treatments are analgesics is not well taken. There is no express support for such a position in Griffin, and, as discussed, such a position does not inherently follow from Griffin's

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teachings. Indeed, by characterizing one agent as a sore throat treatment in one breath, and the other agent as a pain reliever in the next breath, Griffin teaches away from the two agents being the same, i.e., analgesics.

Even if the sore throat treatment could be an analgesic, there is no teaching or suggestion in Griffin that sore throat treatment should be a locally acting analgesic and the pain reliever a systemically acting analgesic, or vice versa. Consequently, Griffin still would not have motivated a person having ordinary skill in the art to the present invention.

In view of the foregoing, Applicants submit that the Examiner would be fully justified to reconsider and to withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is earnestly solicited.

Claims 1-12 were rejected under 35 USC § 103(a) as being obvious over Griffin in view of Nelson. In response, Applicants respectfully request that the Examiner reconsider and withdraw this rejection as well.

The Examiner in the middle paragraph on page 3 of the Office Action takes the position that dextromethorphan is acting like or has the properties of an analgesic. The Examiner does not really make clear exactly what modifications in the two references are necessary to achieve

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the present invention, and this could not be clarified during the interview. However, the rejection appears to be dependent upon the Examiner's characterization of dextromethorphan as being an analgesic.

In response, Applicants would call the attention of the Examiner to the attached excerpt from *Basic and Clinical Pharmacology*, 5th Edition, (1992), page 433, wherein it is taught in no uncertain terms that "Dextromethorphan * * * is essentially free of analgesic * * * properties." Consequently, whatever effect dextromethorphan has in the context of Nelson's invention, those effects are not brought about by any analgesic properties of dextromethorphan. In this regard, Applicants emphasize that Nelson was published long before 1992, and had dextromethorphan been confirmed to have analgesic properties, this would have been expected to have been noteworthy in the excerpt from *Basic and Clinical Pharmacology*. The fact that this well known textbook makes no mention of dextromethorphan's analgesic properties, and, indeed, says it has none, is an indication that persons skilled in the art regard dextromethorphan as not having any analgesic properties.

This also confirms Applicants' point made above that the mouth can be treated with compounds other than analgesics.

In view of the foregoing, Applicants submit that the Examiner would be fully justified to

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reconsider and to withdraw this rejection as well. An early notice that this rejection has been reconsidered and withdrawn is, therefore, earnestly solicited.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

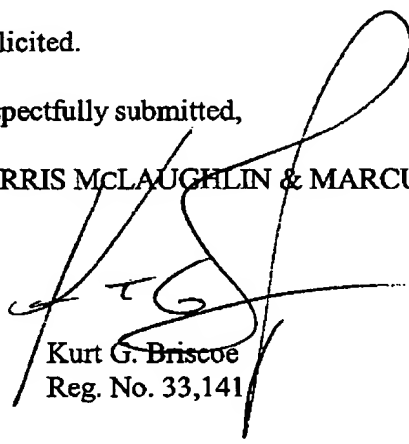
Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.116 and the attached Excerpt from Basic & Clinical Pharmacology and Petition for Extension of Time (13 pages total) are being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: August 12, 2002

By


Kurt G. Briscoe